

REMARKS

Applicants elect to prosecute Claims 11-21, grouped by the Examiner as Group III in the Paper No. 8 dated November 14, 1995. Applicants respectfully traverse this election requirement. However, to facilitate prosecution on the merits, applicants hereby cancel Claims 1-10 and 22-27. Additionally, Claims 11, 12 and 14 are canceled. Therefore upon acceptance and entry into the record, Claims 13 and 15-21 will be in this case. Applicants have amended Claim 13 to include the required SEQ ID NO. Applicants have amended Claims 13 and 15 to point out that the nucleic acid molecule encodes the mature human mpl ligand having the biological property of stimulating proliferation, differentiation and maturation of cells containing human mpl. Support for this language can be found on page 20, line 16 and page 25, lines 27-33. Applicants have amended Claim 19 to insert language found in Claims 20 and 21. Finally Applicants have amended all claims to depend from the proper noncanceled claims.

Accordingly, applicants submit no new matter has been added. Applicants respectfully request reconsideration under 37 C.F.R. § 1.111 in view of these amendments and explanation below.

Double Patenting Rejection

Applicants acknowledge the potential for double patenting with respect to the applications set forth by the Examiner on page 6 and 7 of the Paper No. 8. This is a provisional rejection however and Applicants will cancel claims or file terminal disclaimers as necessary to avoid double patenting when a case is ready for allowance.

Objections and Rejections Under 35 U.S.C. §112

1. The Examiner objected to the use of the term "mpl ligand polypeptide." Applicants have removed the word "polypeptide" when referring to the mpl ligand in all claims being prosecuted.
2. The Examiner has rejected Claims 11-21 under the first paragraph of 35 U.S.C. §112 for various reasons set forth on pages 8-11 of Paper No. 8, primarily for the proposition that the claims, as presented, are not enabled or that the enablement is not commensurate with the scope of the claims. More specifically, the Examiner has objected to the language of the claims and states, for example, on page 10

"...the claims do not positively identify the nucleic acids which are the basis for the currently claimed invention, but rather define such in terms of a partial sequence without regard to function, or the function of encoding protein with particular, ill defined properties."

Applicants have amended Claims 13 and 15 to positively identify the human nucleic acid sequence or amino acid sequence of the amino terminus exon identified in Fig. 7. As suggested in the above quoted comment by the Examiner, Applicants have added language to define the

biological function and properties of the human mpl ligand, namely stimulating proliferation, differentiation or maturation of cells that contain the receptor for the mpl ligand.

Next, regarding scope, Applicants have removed language referring to "hybridization" which the Examiner objected to on page 10, paragraph 3, through page 11, paragraph 3. Applicants believe extending the scope of claims to DNA that hybridizes under stringent conditions with DNA encoding naturally occurring human mpl ligand is not unduly broad and provides reasonable breadth to the claims. However, these claims are withdrawn to advance prosecution of claims directed to the full length naturally occurring human mpl ligand defined by the claims as amended.

Similarly, the Examiner rejected the originally presented claims as being not commensurate in scope with the amount of enablement provided because the claims read on nucleic acids that encode the full length naturally occurring mpl ligand (ml)

"as well as various unspecified and non-described truncations, deletions, and alterations, of such sequences as well as innumerable proteins which might be only distantly related or unrelated which happen to meet the 'limitations'."

Applicants have amended the originally presented claims to remove reference to such "distantly related" variant forms of the naturally occurring mpl ligand.

The Examiner expressed concern over the account of obtaining a clone containing human mpl ligand in the paragraph bridging pages 7 and 8 of Paper No. 8. The description in the specification of this procedure is the way the instant inventors proceeded to obtain the human mpl clone. However, as pointed out by the Examiner, it is the human sequence provided in Fig. 7 which is the key to enablement of the claims as amended and not the description of the way the instant inventors actually arrived at the human mpl ligand sequence.

Given the correct codon sequence for exon 2 encoding both the leader sequence and 26 amino acid residues of the amino terminus of human mpl ligand provided in Figure 7, Applicants submit the claims as amended are adequately enabled and that the scope of enablement is commensurate with the breadth of claims. The Examiner points out on page 8 that the specification does not identify the complete coding sequence nor the complete protein sequence encoded thereby. While this is true, never-the-less Applicants submit the claims, as amended, defining the full length mature human sequence are adequately enabled. Applicants urge that the term Enablement is not equivalent to the term made. Applicants submit that when the test for Enablement, set forth in *Ex parte Forman* (referred to by the Examiner at the bottom of page 9) is evaluated, Applicants' claims are adequately enabled. This is because this invention was described in 1994, a time when the art of recombinant technology was significantly advanced, especially in view of the skill of the routiner in this field. Further, the exact DNA sequence of a long sequence

of human mpl ligand is provided in Fig. 7. Many commercial sources exist for human tissue (e.g., Clontech) as well as premade c-DNA libraries made from human kidney, liver, spleen and other tissues. Further, commercial kits are available employing RACE-PCR (see enclosed Clontech "3'-AmpliFINDER RACE kit) which can be used to PCR a full length c-DNA encoding human mpl ligand. Applicants wish to establish for the record that such a technique is not an obscure method but rather one well known to those skilled in the art. A Supplemental Information Disclosure Statement is provided in which the Rapid amplification of c-DNA encodes (RACE) techniques has been used in a variety of situations to obtain full length sequence.


Applicants urge the Examiner to consider the "Forman factors" when evaluating enablement and to apply them to the instant invention where the level of skill is high, the art is advanced and the amount of information provided in Fig. 7 is significantly more than necessary to enable the claims as amended.

Respectfully submitted,

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